

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-05 MED-03 RSC-01 /026 R

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DHEW/OIH/MACODDING

ARA/EP - MR CLARKE INFO

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R 271952Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY QUITO

AMEMBASSY SAN SALVADOR

AMEMBASSY GUATEMALA

UNCLAS STATE 018785

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, EC, ES, GT

SUBJECT: RECALL OF MEDICAL DEVICE - DEFIBRILLATOR

1. FDA ADVISES THAT THE ISOLATED DC DEFIBRILLATOR, MODEL ISD-24, MANUFACTURED BY ELECTRONICS FOR MEDICINE, INC., 30 VIRGINIA ROAD, WHILE PLANS, NEW YORK 10603 IS BEING RECALLED FROM THE MARKET FOR MODIFICATION BECAUSE OF AN ELECTRONIC HAZARD. THE MODEL NUMBER APPEARS ON THE LOWER RIGHT FRONT PANEL. OF THE 25 UNITS INVOLVED, FOUR WERE FOR FOREIGN DISTRIBUTION.

2. THE DEFIBRILLATOR CAN BE USED FOR EXTERNAL OR INTERNAL USE. IT CAN BE SET UP WITH PANELS FOR ADULT, CHILD, OR INFANT USE. IT CAN BE USED FOR EMERGENCY (UNSYNCHRONOUS) OR SYNCHRONIZED CARIOVERSION. SYNCHRONOUS CARDIOVERSION IS ACCOMPLISHED WITH AN ELECTRONICS FOR MEDICINE PATIENT MONITOR OR EKG RECORDER HAVING AN ECG TACHOMETER/AMPLIFIER OR TRIGGER UNIT PROVIDING A SYNCHRONIZING OUTPUT. ROUTINE TESTING BY THE FIRM UNCOVERED A POSSIBLE PROBLEM WHEN THE MODEL ISD-24 DEFIBRILLATOR WAS USED FOR SYNCHRONIZED CARDIOVERSION. NO PROBLEM EXISTS WHEN THE UNIT

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IS USED FOR EMERGENCY DEFIBRILLATION. THEIR TESTING REVEALED

THAT THERE WAS APPROXIMATELY A ONE IN A ONE HUNDRED CHANCE THAT THE MODEL ISD-24 MIGHT FIRE PREMATURELY WHEN USED IN CARDIOVERSION. THE MODEL ISD-24 IS DESIGNED TO FIRE TWELVE MILLISECONDS AFTER THE QRS WAVE OCCURS. THEIR TESTING SHOWED THAT THE MODEL ISD-24 MIGHT FIRE BEFORE THE QRS WAVE WHEN USED IN CARDIOVERSION. THE PROBLEM WAS RELATED TO A SILICON CONTROL RECTIFIER. THE MODEL ISD-24 WHEN USED IN SYNCHRONIZED CARDIOVERSION COULD FIRE BY A RATE CHANGE IN VOLTAGE. THIS WAS REFERRED TO AS A STRAY COUPLING EFFECT IN THE SILICON CONTROL RECTIFIER. A RESISTOR WAS ADDED TO THE UNITS THAT WERE DISTRIBUTED. THIS RESISTOR HOLDS THE CATHODE AT A KNOWN POTENTIAL. IT CORRECTS THE PROBLEM. THE FIRM STATED THAT THE USE OF THE MODEL ISD-24 IN EMERGENCY DEFIBRILLATION WOULD NOT BE AFFECTED BY THIS PROBLEM.

3. FOREIGN DISTRIBUTION, AS FOLLOWS:

CLINICA PICHINCHIA, QUITO, ECUADOR, ONE UNIT.

GOVERNMENT OF EL SALVADOR, (GOBIERNO EL SALVADOR), SAN SALVADOR, EL SALVADOR, ONE UNIT.

BENJAMIN BLOOM HOSPITAL, SAN SALVADOR, EL SALVADOR, ONE UNIT.

HOSPITAL GENERAL SAN JUAN DE DIES, GUATEMALA CITY, GUATEMALA, ONE UNIT.

THE UNIT BOUND FOR ECUADOR WAS MODIFIED ON THE PIER IN PORT OF NEWARK WHILE IN TRANSIT. THE UNITS SHIPPED TO THE TWO CONSIGNEES IN SAL SALVADOR WILL BE MODIFIED BY THE ELECTRONICS FOR MEDICINE FIELD REPRESENTATIVE WHO IS GOING TO SAN SALVADOR TO INSTALL THE EQUIPMENT. THE UNIT IN GUATEMALA WILL BE MODIFIED BY THE FIRM'S SALES AGENT THERE.

4. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF UNITS HAVE BEEN MODIFIED ACCORDING TO FIRM'S INSTRUCTIONS. KISSINGER

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To: QUITO GUATEMALA
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